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Flex-Lase 600 Series Ion Laser
American Laser Medical
November 7, 1996

Summary of Safety and Effectiveness Information

Regulatory Authority:

Safe Medical Devices Act of 1990, 21 CFR 807.92

Company Name/Contact;

Company: American Laser Medical
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Regulatory Affairs
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Name of Device:

Trade Name: Flex-Lase 600 Series Ion Laser

Common Name: Dermatology Laser

Classification:

Powered surgical laser instruments are assigned the unique device classification code 79GEX. The published physical description of this device is found in 21 CFR, § 878.4810 (a) (2). This device classification section specifically describes argon laser systems. The American Laser Medical device may be configured as either an argon laser system or as a krypton laser system, however American Laser Medical maintains that there is no substantial difference between argon and krypton lasers for the purpose of classification. Presently, these lasers are considered Class II medical devices.

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Flex-Lase Model 640 Laser System

For vascular lesions: (Yellow - 568 nm)

1. Capillary Hemangioma (port wine hemangioma)
2. Strawberry hemangioma
3. Telangiectasia
4. Rosacea

For pigmented lesions: (Yellow/Green - 568 nm and 520-530 nm).

1. Freckles
2. Age Spots
3. Cafe-au-lait
4. Lentigo

Flex-Lase Model 620 Laser System

For Vascular Lesions: (Blue/Green - 488 nm and 514.5 nm)

1. Capillary Hemangioma (port wine hemangioma)
2. Strawberry Hemangioma
3. Telangiectasia
4. Rosacea

For pigmented lesions: (Green - 514.5 nm)

1. Freckles
2. Age Spots
3. Cafe-Au-Lait
4. Lentigo

Comparison of Device Characteristics:

For vascular lesions:

The Flex-Lase 600 Ion Laser System is substantially equivalent to the MQM Spectrum K1, the Metalaser Vasculase and the Coherent Artisan already in commercial distribution. The materials, design, intended use, method of manufacture, warnings, cautions, precautions and treatment parameters are substantially the same.

For pigmented lesions:

The Flex-Lase 600 Series Ion Laser system is substantially equivalent to the HGM Spectrum K1, the Metalaser Vasculase and the Coherent Artisan already in commercial distribution. The

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materials, design, intended use, method of manufacture, warnings, cautions and precautions are substantially the same.

Feature comparison tables which follow illustrate the equivalence of features of the Flex-Lase 600 and equivalent available systems. See also appendix II for marketing materials on substantially equivalent devices.

